1 3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM

Date: March 11, 2011

SUBJECT: (RE-ISSUED) Health Effects Division (HED) Review of Agricultural Handler Exposure Task Force (AHETF) Monograph: Open Pour Mixing and Loading Liquid Formulations

PC Code: --
Decision No.: --
Petition No.: --
Risk Assessment Type: --
TXR No.: --
MRID No.: 47947802

DP Barcode: D373605
Registration No.: --
Regulatory Action: --
Case No.: --
CAS No.: --
40 CFR: --

Ver.Apr.08

FROM: Jeff Evans, Biologist
Jeff Dawson, Chemist
Matthew Crowley, Biologist
Health Effects Division

11.mar.2011

THROUGH: David J. Miller, Chief
Chemistry and Exposure Branch
Health Effects Division

TO: Richard Dumas
Pesticide Registration Division

This memorandum presents the Health Effects Division review of the occupational handler exposure scenario monograph "Open Pour Mixing and Loading Liquids Formulations" submitted by the Agricultural Handler Exposure Task Force. It has been corrected to address transcription and typographical errors identified in the original publication (7/1/10). Additionally, references to "interim" dermal exposures have been removed. The exposure data are acceptable and recommended for use in applicable pesticide exposure and risk assessments.

Rec'd in RRC 3/15/2011

I. EXECUTIVE SUMMARY

This document represents the Health Effects Division (HED) review of the Agricultural Handler Exposure Task Force (AHETF) Monograph: Open Pour Mixing and Loading Liquid Formulations (AHETF, 2009). HED confirms that the data meets the study design objectives outlined in the AHETF Governing Document (AHETF, 2007) and is considered the most reliable data for assessing exposure and risk to individuals mixing and loading liquid formulations contained in any open-style packaging into a wide variety of nurse, slurry, and sprayer tanks (e.g., tanks for ground boom, airblast, and aerial equipment) while wearing the following personal protective equipment (PPE): long-sleeved shirts, long pants, shoes, socks, chemical-resistant gloves, and no respirator[1]. This dataset supersedes the current dataset[2] used to assess exposure and risk for open pour mixing and loading liquid formulations.

Select summary statistics for the open pour mixing and loading liquids "unit exposures" are presented in Table 1 below, as well as the PHED value previously used for comparison.

Table 1. Unit Exposures (ug/lb ai handled): Open Pour Mixing and Loading Liquid Formulations

Exposure Route	PHED	AHETF[a, b]		
	"Best Fit"	Geometric Mean	Arithmetic Mean[c]	95th Percentile[d]
Dermal	23	19.8	37.6	127.5
Inhalation	1.2	0.083	0.219	0.822

[a] Dermal unit exposures reflect 50% adjustment of hand and face/neck measurements. The average percent of dermal exposure representing the hands, face, and neck is 46%.
[b] Statistics are estimated using a variance component model accounting for correlation between measurements conducted within the same field study (i.e., measurements collected during the same time and at the same location). Additional model estimates (e.g., empirical and simple random sample assumptions) are described in Section III.
[c] Arithmetic Mean (AM) = GM * exp{0.5*((lnGSD)^2)}
[d] 95th percentile = GM * GSD^1.645

The following important points with respect to these data are noted:

- The AHETF data and associated unit exposures are considered superior to the existing open pour mixing and loading liquids dataset (i.e., PHED data) and its "best fit" unit exposure. AHETF efforts represented a well-designed, concerted process to collect reliable, internally-consistent, and current exposure data in a way that takes advantage of and incorporates a more robust statistical design, better analytical methods, and improved data handling techniques.
- Dermal exposure results reflect the default 50% wash removal efficiency adjustment (i.e., a factor of 2X) used to correct hand and face/neck measurements when their contribution to overall exposure is 20% - 60%. Additional information or data on the efficiency of the hand wash and face/neck wipe methods may waive this default adjustment and modify the exposure results. Inhalation exposure results are final, as they are not subject to pending measurement method efficiency adjustments.

[1] Adjustments to this dataset to represent alternative personal protective equipment (e.g., applying reduction or protection factors to reflect the addition or removal of protective clothing, gloves, respirators, etc.) are not included in this review.
[2] Pesticide Handlers Exposure Database (PHED) Scenario 3: All Liquids, Open Mixing and Loading (MLOD)

- The data are not applicable for assessment of exposure and risk to highly volatile pesticides (e.g., fumigants).
- Statistical analysis indicates that both dermal and inhalation exposure are not independent of the amount of active ingredient handled and provides support for proportionality – a key assumption in the use of exposure data as "unit exposures". Thus, for this scenario, HED will continue to use the exposure data normalized by the amount of active ingredient as a default condition.

II. BACKGROUND

The AHETF is developing a compensable database representing worker exposure during major agricultural and non-agricultural handler scenarios. A scenario is defined as a pesticide handling task based on activity (e.g., application) and equipment type (e.g., open cab ground boom). Generally, AHETF scenarios represent individuals wearing long-sleeved shirts, long pants, shoes, socks and chemical-resistant gloves. An exception is the use of chemical-resistant headgear for overhead exposure (e.g., open cab airblast applications), for which cloth patches located inside and outside the headgear are used to measure head exposure.

In this case, the scenario is open pour mixing and loading liquid formulations into a wide variety of nurse, slurry, and sprayer tanks (e.g., tanks for ground boom, airblast, and aerial equipment) while wearing the following personal protective equipment (PPE): long-sleeved shirts, long pants, shoes, socks, chemical-resistant gloves, and no respirator. The figures below (from AHETF, 2009) depict examples of this activity for which the exposure data are applicable.

Figure 1: Open Pour Mixing/Loading Liquids – ground boom tank

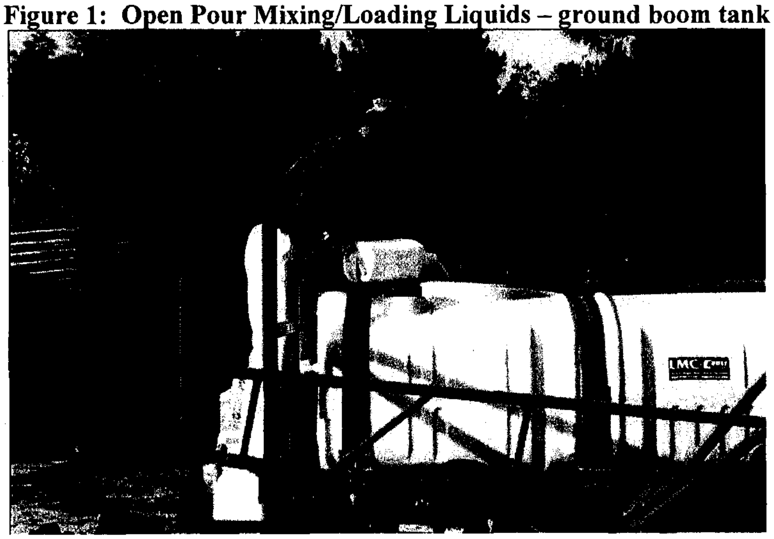


Figure 2: Open Pour Mixing/Loading Liquids – small container into spray tank

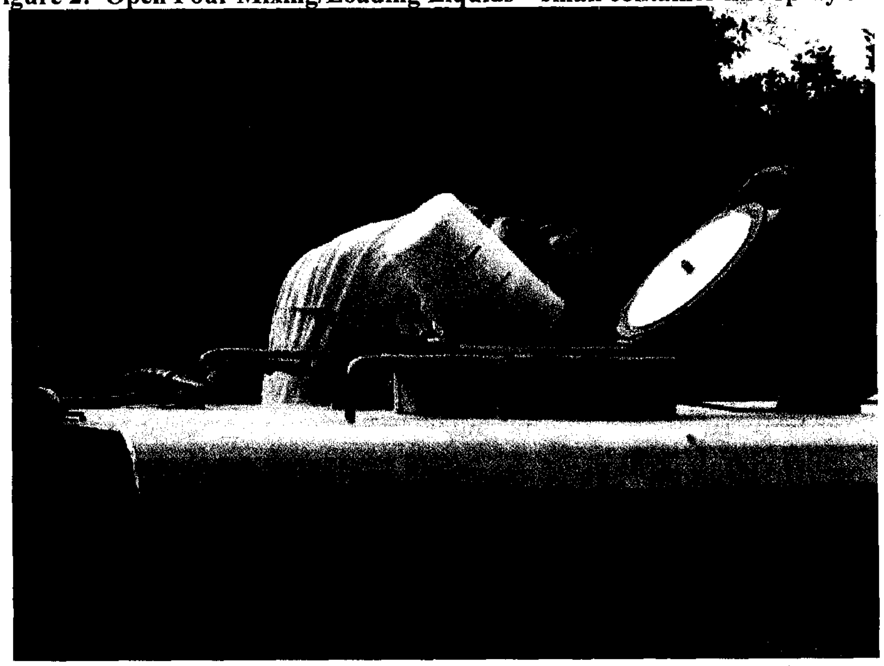
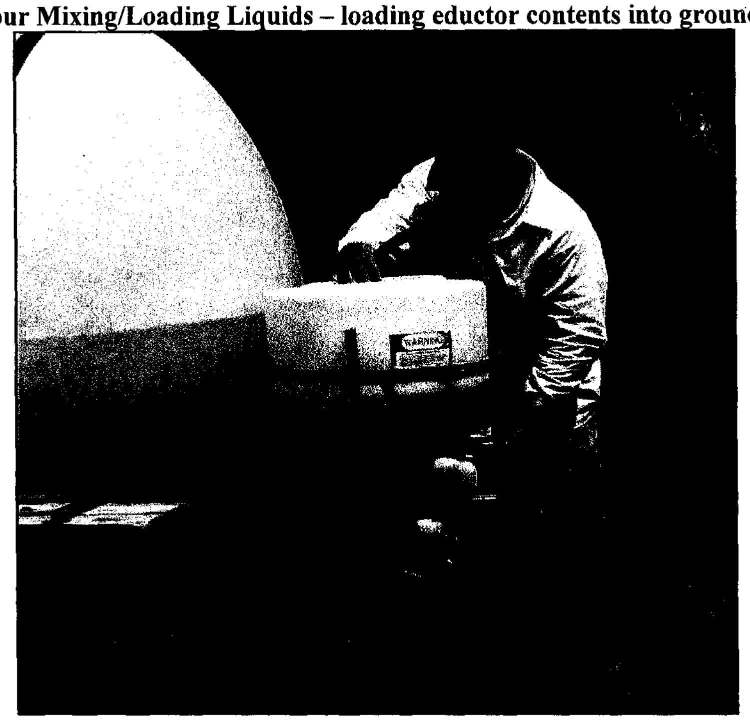


Figure 3: Open Pour Mixing/Loading Liquids – loading eductor contents into ground boom spray tank



Dermal and inhalation exposure monitoring was conducted for workers mixing and loading liquid formulations and expressed, for use in exposure assessments, as "unit exposures". A "unit exposure" (UE) is defined as the expected external chemical exposure an individual may receive (i.e., "to-the-skin" or "in the breathing zone") per weight-unit chemical handled and is the default data format used in pesticide handler exposure assessments. Mathematically, unit exposures are expressed as "handler" exposure normalized by the amount active ingredient handled (AaiH) by participants in scenario-specific exposure studies (e.g., mg exposure/lb ai handled). These UEs are then used generically to model exposure for other chemicals having the same or different application rates.

Two major assumptions underlie the use of exposure data in this fashion. First, the expected external exposure is unrelated to the active ingredient in the pesticide formulation. That is, the physical characteristics of the pesticide formulation (e.g., formulation type – wettable powder, liquid concentrate, dry flowable, etc.) or the equipment type used to apply the pesticide influence exposure more than the specific pesticide active ingredient (Hackathorn and Eberhart, 1985). Thus, for example, exposure data for mixing and loading one chemical formulated as a wettable powder can be used to estimate exposure for another chemical formulated as a wettable powder. Second, dermal and inhalation exposure are assumed proportional to the amount of active ingredient handled. In other words, if one doubles the amount of pesticide handled, one doubles the exposure.

The AHETF developed criteria reviewed by HED and presented to the Human Studies Review Board (HSRB) for determining when a scenario is considered complete and operative. Outlined in the AHETF Governing Document (AHETF, 2007), the criteria can be briefly summarized as follows:

- The primary objective of the study design is to be 95% confident that key statistics of normalized dermal exposure are accurate within 3-fold. Specifically, the upper and lower 95% confidence limits should be no more than 3-fold higher or lower than the estimates for each the geometric mean, arithmetic mean, and 95th percentile dermal unit exposures. To meet this primary objective AHETF proposed an experimental design that provides a sufficient number of field trials and a sufficient number of monitored individuals. Note that this "fold relative accuracy" objective does not apply to normalized inhalation exposure, though estimates are provided for reference (see Table 4).

- A secondary objective is to evaluate the assumption of proportionality between exposure and AaiH in order to be able to use the AHETF data generically across application rates. To meet this objective, the AHETF proposed a log-log regression test to distinguish complete proportionality (slope = 1) from complete independence (slope = 0), with 80% statistical power, achieved when the width of the 95th confidence interval of the regression slope is 1.4 or less. Note, again, that this objective does not apply to normalized inhalation exposure; however the tests are performed for informational purposes.

- To achieve both the primary and secondary objectives described above, the AHETF developed a study design employing a 'cluster' strategy. Each cluster is defined by a region. Typically, these regions are defined by a few contiguous counties in a given state(s) within a US EPA growing region. For most handler scenarios a configuration of 5 regional clusters consisting of 5 participants is used to meet the objectives from a statistical sample size perspective. The 25 total participants and the conditions under which the worker handles the active ingredient are referred to as monitoring units (MUs). Within each cluster, the AHETF partitions the practical AaiH range handled by the participants in each cluster appropriate to a given scenario. In general, the strata of AaiH for any given scenario is commensurate with the assumptions HED uses in handler risk assessments with respect to acres treated (e.g., 200 acres treated for ground boom applications for an 8 hour work day).

III. RESULTS

The data for the open pour mixing and loading liquids scenario were collected prior to the development of the AHETF Governing Document which established the statistical benchmark objectives outlined above in Section II. Thus, the sampling design and configuration of MUs is slightly different than outlined in the Governing Document, though the resulting number of MUs is 25. Four field studies conducted by the AHETF (studies AHE30, 31, 32, and 40) ranged from 2 – 6 MUs per study. Existing mixing and loading liquid formulation exposure data (8 MUs; including repeat measures on different days) was purchased by the AHETF (study AH501-M-2). The breakdown of field studies and number of MUs is as follows:

- AHE30 (EPA MRID 47309201) – 2 MUs
- AHE31 (EPA MRID 47309202) – 3 MUs
- AHE32 (EPA MRID 47309203) – 6 MUs
- AHE40 (EPA MRID 47309204) – 6 MUs
- AH501-M-2 (EPA MRID 42685901) – 8 MUs

While the sampling in this scenario does not reflect the current AHETF standard 5X5 design, it does possess many of the other sampling strategies outlined in the AHETF Governing Document, such as:

- representing the diversity of equipment types commonly assessed in Agency assessments of mixing and loading liquid formulations;
- including a variety of tanks including nurse and eductor systems as well as various application equipment tanks (e.g., ground boom, airblast, and aerial equipment);
- remaining consistent with the range of AaiH expected to be handled for an activity such as open pour mixing and loading; and,
- meeting the statistical benchmark objectives.

Calculating Unit Exposures

Dermal exposure is measured using 100% cotton "whole body dosimeters" (WBD) underneath normal work clothing (i.e., long-sleeved shirt, long pants, socks and shoes), hand rinses (collected at the end of the day and during restroom and lunch breaks), and face/neck wipes. The WBD is sectioned and analyzed by body part (i.e. upper and lower arms, upper and lower legs, etc.). For study AH501-M-2, whole body dosimeters were used, however were not separated into the six distinct body regions – they were analyzed as upper and lower body regions. Additionally, exposure to the head was measured using cloth patches which were then extrapolated to the entire head. All samples are adjusted as appropriate according to recovery results from field fortification samples. Total dermal exposure (e.g., milligrams active ingredient) is calculated by summing exposure across all body parts for each individual monitored. Dermal unit exposures (i.e., mg/lb ai handled) are then calculated by dividing the summed total exposure by the amount of active ingredient handled.

Inhalation exposure is measured using a personal air sampling pump and an OSHA Versatile Sampler (OVS) tube with a glass fiber filter and Chromosorb 102 solvent. The tube is attached to the worker's collar to continuously sample air from the breathing zone. Collected residue, per standard practice, is adjusted for recovery from field fortification samples. Inhalation exposures are calculated by adjusting the measured air concentration (i.e., ug/L) for a worker's breathing rate – assumed 16.7 liters per minutes (LPM; converted from 1.0 m^3/hr), representing light activities such as mixing/loading light packages (NAFTA, 1998) – and total work/monitoring time:

Inhalation Exposure (ug) = collected air residue (ug) x [breathing rate (L/min) ÷ average pump flow rate (L/min)]

Inhalation unit exposures (i.e., mg/lb ai handled) are calculated by dividing the inhalation exposure by the amount of ai handled by the individual study participant.

Dermal and Inhalation Exposure Results

A summary of the 25 MUs and their dermal and inhalation UEs for the open pour mixing and loading liquids scenario are presented in Table 3 below. For dermal unit exposures, both the hand wash and face/neck method efficiency adjusted (MEA) data and non-adjusted (non-MEA) are presented. All field studies conducted by the AHETF include the recording of individual participant activities by field observers. Select observations are included in Table 3 to provide examples of "real world" events during open mixing and loading liquid formulations.

Note that for the study purchased by the AHETF (AH501-M-2), 5 MUs are represented by a single worker ("M") and the remaining 3 MUs by another ("N"). Worker "M" mixed and loaded liquids twice on one day, then once each on 3 days. Worker "N" mixed and loaded liquids once each on 3 days. Additionally, all MUs in study AH501-M-2 loaded a 55 gallon tank whose contents were subsequently pumped into a 500 gallon airplane tank. More detailed MU-specific exposure data are presented in Attachment 1.

Table 3. Open Pour Mixing and Loading Liquids Scenario: MU Summary

AHETF Participant	State	Work/ Monitoring Time (hours)	Tank Type	Tank Size (gallons)	Tank Loads Mixed (#)	AaiH (lbs)	Unit Exposure (ug/lb ai)		
							Dermal[a]		Inhalation[a]
							MEA[b]	Non-MEA	
AH501-M-2-M1-M	MS	2.8	Premix-aerial	55	5	346	3.9	3.5	0.024
AH501-M-2-M3-M	MS	3.0	Premix-aerial	55	7	493	2.9	1.9	0.019
AH501-M-2-M5-M	MS	2.2	Premix-aerial	55	2	124	6.9	5.9	0.055

AH501-M-2-M7-M	MS	1.6	Premix-aerial	55	3	116	18.1	10.5	0.004
AH501-M-2-M8-M	MS	3.0	Premix-aerial	55	4	241	10.1	6.7	0.077
AH501-M-2-M2-N	MS	2.0	Premix-aerial	55	3	186	5.9	4.4	0.010
AH501-M-2-M4-N	MS	1.6	Premix-aerial	55	3	107	9.9	7.0	0.004
AH501-M-2-M6-N	MS	3.8	Premix-aerial	55	4	233	26.6	16.7	0.083
AHE30-M1	OR	5.5	Ground boom	50 & 100	11	72.2	5.7	3.2	0.028
AHE30-M2	OR	9.8	Ground boom	100	19	219	36.0	22.5	0.119
AHE31-M1	CA	6.5	Ground boom	300	5	138	123	116	0.268
AHE31-M2	CA	5.0	Ground boom	300	5	155	42.6	30.2	0.238
AHE31-M3	CA	7.3	Ground boom	300	19	407	63.0	42.9	0.429
AHE32-M1	FL	3.8	Ground boom	1200	2	72.1	56.3	42.6	0.061
AHE32-M2	FL	7.4	Ground boom	225	8	408	5.3	4.2	0.082
AHE32-M3	FL	4.0	Ground boom	225	4	204	6.4	4.2	0.050
AHE32-M4	GA	6.0	Ground boom	300	5	263	63.3	37.0	0.017
AHE32-M5	GA	6.2	Ground boom	30	15	88.1	34.2	20.7	0.056
AHE32-M6	GA	4.2	Ground boom	200	3	132	24.3	13.9	0.067
AHE40-M1	GA	5.5	Ground boom	200	4	10.2	21.4	11.6	0.163
AHE40-M2	GA	7.3	Ground boom	500	4	501	7.3	5.7	0.141
AHE40-M3	GA	6.7	Ground boom	300 & 500	4	611	7.5	5.2	0.069
AHE40-M4	GA	5.2	Ground boom	200	4	19.0	91.8	60.5	0.531
AHE40-M5	GA	10.2	Ground boom	200	9	40.1	22.6	17.8	0.493
AHE40-M6	GA	7.0	Ground boom	200	6	30.6	64.2	48.4	0.415

[a] See Attachment 1 – Table 1 for additional exposure details.
[b] Values reflect use of the 50% default adjustment for hands and face/neck measurements.

Select Field Notes

- AHE30-M2: Leaned on spray tank and looked in tank. Reached into tank to remove the rubber gasket.
- AHE31-M3: Mixer poured chemical directly into tank, then triple rinsed bottle or measuring container with hose at knee level. Mixer's arm rests on top of tank when pouring chemical from containers or adding water with hose, but reaches arm inside tank when pouring rinse water.
- AHE32-M6: Opened filter for Applicator 6 sprayer under the rear of the tank. Used a garden hose to wash the filter and replaced it. Climbed on the tank sprayer and opens and closes lid. Reaches under sprayer to adjust a valve. Climbed back on sprayer opens lid. Sprayer agitation is working. Closes tank lid and climbs down. Used a garden hose to wash gloves and spray down the cement pad.

Evaluation of Scenario Benchmark Objectives

The AHETF monograph details the extent to which the open pour mixing and loading liquid formulations scenario meets the current AHETF scenario objectives. Note that though the data were not developed under current study design objectives outlined in the AHETF Governing Document, the AHETF analyzed the data as if it were subject to these guidelines. HED has independently confirmed the AHETF results (Sarkar, B., 6/25/10; D000000) and agrees that the objectives have been met for this scenario.

Primary Benchmark Objective: fold Relative Accuracy (fRA)

The primary benchmark objective for AHETF scenarios is that select statistics – the geometric mean (GM), the arithmetic mean (AM), and the 95th percentile (P95) – are accurate to within 3-fold with 95% confidence (i.e., "fold relative accuracy"). The AHETF analyzed the data using various statistical techniques to evaluate this benchmark. First, to characterize the unit exposures (also referred to as "normalized exposure"), AHETF demonstrated that dermal and inhalation UEs (unadjusted for residue method collection efficiencies) appear to be lognormally distributed as shown by the reasonably straight-line fits in the lognormal probability plots below.

Figure 4: Lognormal Probability Plot of Dermal Unit Exposures (AHETF, 2009; pg. 126)

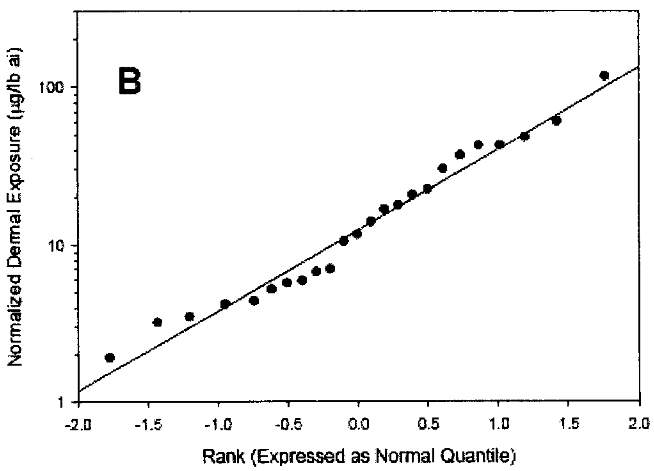
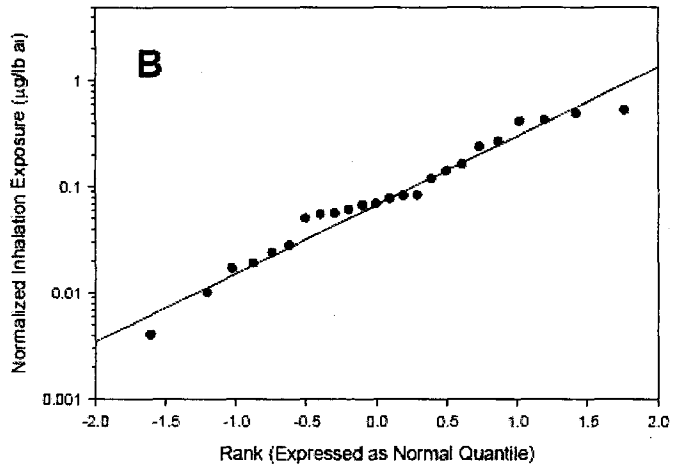


Figure 5: Lognormal Probability Plot of Inhalation Unit Exposures (AHETF, 2009; pg. 127)



Next, the AHETF calculated estimates of the GM, AM and P95 based on three variations of the data:

- Non-parametric empirical (i.e., ranked) estimates;
- Assuming a lognormal distribution and a simple random sample (SRS); and,
- Hierarchical variance component modeling to account for potential MU correlations.

The 95% confidence limits for each of these estimates were obtained by generating 10,000 parametric bootstrap samples. Then, the fRA for each was determined as the maximum of the two ratios of the statistical point estimates with their respective upper and lower 95% confidence limits. Table 4 below presents the results.

Table 4. Results of Primary Benchmark Analysis

	Dermal Exposure[a]			Inhalation Exposure		
Statistic	**Unit Exposure Estimate (ug/lb ai)**	**95% CI**	**fRA**	**Unit Exposure Estimate (ug/lb ai)**	**95% CI**	**fRA**
GM_S	18.0	9.6 – 41.2	2.3	0.068	0.028 – 0.252	3.7
GSD_S	2.97	2.11 – 4.40	1.5	3.95	2.21– 6.96	1.8
GM_M	19.8	9.9 – 39.7	2.0	0.083	0.03 – 0.227	2.8
GSD_M	3.10	2.13 – 4.82	1.6	4.04	2.27 – 8.00	2.0
ICC	0.29	0.00 – 0.68	--	0.54	0.00 – 0.85	--
IDC	0.30	0.00 – 0.78	--	0.68	0.01 – 0.91	--
GM_S = geometric mean assuming SRS = "exp(average of 25 ln(UE)) values" GSD_S = geometric standard deviation assuming SRS = "exp(standard deviation of 25 ln(UE)) values" GM_M = variance component model-based geometric mean GSD_M = variance component model-based geometric standard deviation ICC = 'intra-cluster' correlation (i.e., within study correlation) IDC = 'intra-day' correlation (i.e., within day correlation)						
AM_S	30.4	15.6 – 82.0	2.7	0.140	0.053 – 0.655	4.7
AM_U	32.5	16.1 – 85.7	2.6	0.175	0.056 – 0.839	4.8
AM_M	37.6	16.8 – 92.4	2.5	0.219	0.062 – 1.012	4.6
AM_S = average of 25 unit exposures AM_U = arithmetic mean based on GM_S = GM_S*exp{0.5*((lnGSD_S)^2)} AM_M = variance component model-based arithmetic mean = GM_M* exp{0.5*((lnGSD_M)^2}						
$P95_S$	91.8	39.5 – 313.9	3.4	0.493	0.146 – 3.006	6.1
$P95_U$	107.5	47.1 – 309.6	2.9	0.651	0.173 – 3.088	4.7
$P95_M$	127.5	49.1 – 341.4	2.7	0.822	0.193 – 3.671	4.5
$P95_S$ = 95th percentile (i.e., the 24th unit exposure out of 25 ranked in ascending order) $P95_U$ = 95th percentile based on GM_S = GM_S * GSD_S^1.645 $P95_M$ = variance component model-based 95th percentile = GM_M* GSD_M^1.645						
[a] Dermal exposure values reflect 50% default adjustment for hands and face/neck measurements.						

The benchmark of 3-fold accuracy for dermal unit exposures has been met for this scenario and the analysis confirmed independently by HED. Note, though not applicable to the benchmark, the fRA values for inhalation are sometimes higher than those for dermal exposure. Additionally, the primary objective was met regardless of whether the hand and face/neck samples were adjusted or not adjusted using HED's default 50% method efficiency correction.

Secondary Benchmark Objective – the relationship between exposure and AaiH

The secondary statistical benchmark of AHETF studies is to be able to distinguish, with 80% statistical power, complete proportionality from complete independence between exposure and amount of active ingredient handled. Recall that this benchmark applies only to dermal exposure, but analysis was performed on inhalation exposure as well and presented for informational purposes.

To evaluate the relationship for this scenario the AHETF performed regression analysis of ln(exposure) and ln(AaiH) to determine if the slope is not significantly different than 1 – indicating a proportional relationship – or if the slope is not significantly different than 0 – indicating an independent relationship. Since these data were collected prior to the study design outlined in the AHETF Governing Document (AHETF, 2007), which established the goal of 80% power, a post hoc power assessment was performed to see if this benchmark was achieved.

Both simple linear regression and mixed-effect regression were performed to evaluate the relationship between dermal exposure (unadjusted for exposure method collection inefficiencies) and AaiH. The resulting regression slopes and confidence intervals are summarized in Table 5 and in Figures 6 and 7 below. Note that a confidence interval width of 1.4 (or less) indicates at least 80% statistical power and those for simple linear regression are only valid if between-MU correlations are absent.

Table 5. Summary Results of log-log Regression Slopes

Regression Model	Dermal Exposure			Inhalation Exposure		
	Estimate	95% CI	CI Width	Estimate	95% CI	Width
Simple Linear	0.58	0.16 – 0.99	0.83	0.62	0.06 – 1.17	1.10
Mixed-Effects	0.59	0.19 – 0.99	0.81	0.87	-0.53 – 1.21	0.68

Figure 6: Dermal Exposure Regression (AHETF, 2009; pg. 143)

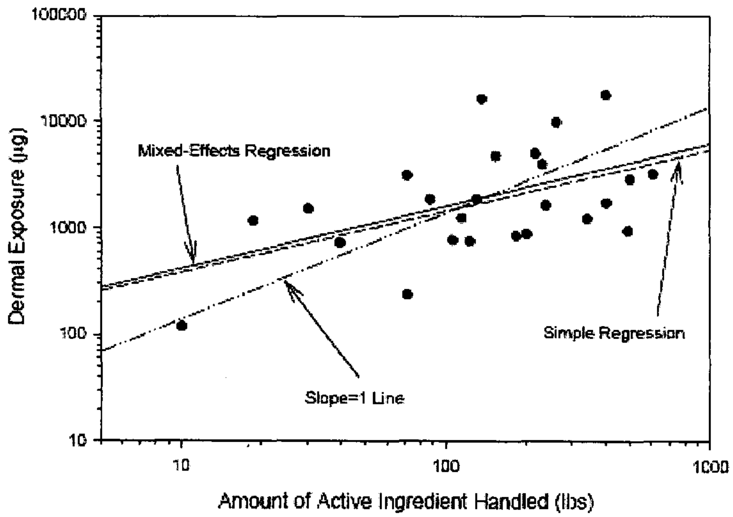
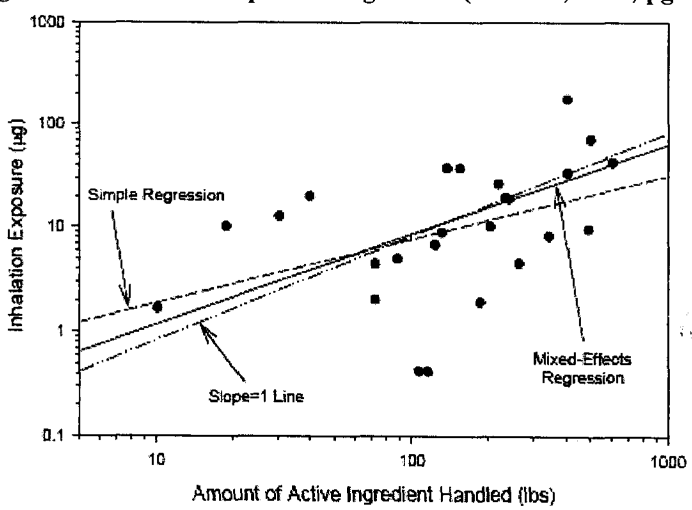


Figure 7: Inhalation Exposure Regression (AHETF, 2009; pg. 143)



The regression results show that for both dermal and inhalation exposure, while the log-log regression slopes are less than 1 the 95% confidence intervals include 1 while excluding 0, indicating that proportionality is a reasonable assumption. With confidence interval widths in all cases less than 1.4, the secondary benchmark of determining proportionality or independence between exposure and AaiH with 80% statistical power was met for this scenario and the analysis confirmed independently by HED. Additionally, this objective was met regardless of whether the hand and face/neck samples were adjusted using HED's default 50% method efficiency correction.

IV CONCLUSION

HED has reviewed the AHETF Open Pour Mixing and Loading Liquid Formulations monograph and concurs with the technical analysis of the data as well as the evaluation of the statistical benchmark objectives (Sarkar, B., 6/25/10; D000000). The following is a summary of our conclusions.

- Deficiencies in the existing open pour mixing and loading liquids PHED dataset used to calculate unit exposures have been recognized and the need for new data established.
- The AHETF data developed and outlined in the monograph and this review represent the most reliable data for assessing open pour mixing and loading liquids exposure.
- Though these data were developed prior to AHETF adoption of statistical analysis benchmarks, it was evaluated with respect to, and demonstrated to meet, these objectives. Estimates of the GM, AM, and P95 were shown to be accurate within 3-fold with 95% confidence and the data provided 80% statistical power to distinguish complete proportionality or independence between exposure and AaiH.
- Evidence to support the assumption of proportionality between both dermal and inhalation exposure and the amount of active ingredient handled was found. As a result, HED will continue using exposures normalized by AaiH as a default condition.

V REFERENCES

AHETF, 2007. Governing Document, Human Research Monitoring Program, Draft version dated May 22, 2007, Agricultural Handlers Exposure Task Force (AHETF). [MRID47172401]

AHETF, 2009. Agricultural Handler Exposure Scenario Monograph: Open Pour Mixing and Loading of Liquid Formulations. Original dated March 24, 2009. Amended December 29, 2009. [MRID 47947802]

Christian, Myrta, 2007. Memorandum: Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held January 9 – 12, 2007 on the Review of Worker Exposure Assessment Methods. U.S. Environmental Protection Agency.

Hackathorn, D.R. and D.C. Eberhart. 1985. Data Base Proposal for Use in Predicting Mixer-loader-applicator Exposure. American Chemical Society Symposium Series 273, pp. 341-355.

NAFTA - Dept. of Pesticide Regulation (DPR), California EPA, HSM-98014, April 24, 1998.

Sarkar, Bayazid, 2010. Memorandum: Review of Statistical Analyses in Agricultural Handler Exposure Task Force (AHETF) Monographs. U.S. Environmental Protection Agency. June 25, 2010. D000000.

Attachment 1

AHETF Open Pour Mixing and Loading Liquid Formulations: MU Inhalation and Dermal Exposure[a] Data Details																	
		Inhalation				Dermal											
MU ID	AaiH (lbs)	Field Recovery Adjusted OVS Total (ug/sample)	Avg. Pump Flow (L/min)[b]	Exposure (ug)[c]	Unit Exposure (ug/lb ai)[d]	Field Recovery Adjusted body part-specific Residue (ug)[e]						Field Recovery Adjusted Head/Neck Residue (ug)			Field Recovery Adjusted Hand Residue (ug)	Total	
						LA	UA	FT	RT	LL	UL	Face /Neck[f]	Head[g]	Whole Head /Neck[h]		Exposure (ug)[i]	Unit Exposure (ug/lb ai)[j]
AH501-M-2-M1-M	346	0.466	0.95	8.20	0.024	97.0				46.5		--	--	910	145	1199	3.5
AH501-M-2-M3-M	493	0.571	1.00	9.53	0.019	100				97.0		--	--	243	484	924	1.9
AH501-M-2-M5-M	124	0.385	0.95	6.76	0.055	39.0				379		--	--	191	126	735	5.9
AH501-M-2-M7-M	116	0.025	1.00	0.418	0.004	129				213		--	--	2.4	879	1224	10.5
AH501-M-2-M8-M	241	1.12	1.00	18.6	0.077	169				303		--	--	325	819	1616	6.7
AH501-M-2-M2-N	186	0.114	1.00	1.90	0.010	86.7				329		--	--	142	268	826	4.4
AH501-M-2-M4-N	107	0.025	1.00	0.418	0.004	70.1				364		--	--	2.4	315	752	7.0
AH501-M-2-M6-N	233	1.16	1.00	19.3	0.083	934				407		--	--	262	2305	3908	16.7
AHE30-M1	72.2	0.240	2.00	2.00	0.028	19.6	5.1	12.8	4.8	5.4	6.9	46.5	28.3	74.8	102	231	3.2
AHE30-M2	21.9	3.09	1.98	26.1	0.119	618	279	675	179	33.2	183	70.8	43.1	114	2844	4925	22.5
AHE31-M1	138	4.33	1.95	37.1	0.268	13919	211	518	85.6	62.4	179	40.7	24.8	65.5	987	16028	116
AHE31-M2	155	4.30	1.95	36.8	0.238	490	117	629	186	76.7	1258	163	99.1	262	1657	4676	30.2

AHE31-M3	407	20.4	1.95	175	0.429	4300	623	1755	588	269	1790	159	96.7	256	7892	17473	42.9
AHE32-M1	72.1	0.531	2.01	4.41	0.061	250	41.6	1114	156	66.9	446	16.3	9.9	26.2	967	3068	42.6
AHE32-M2	408	4.03	2.01	33.5	0.082	530	73.0	241	54.2	60.7	259	45.8	27.9	73.7	408	1700	4.2
AHE32-M3	204	1.23	2.03	10.1	0.050	76.3	43.9	115	50.2	64.5	61.8	38.2	23.2	61.4	386	859	4.2
AHE32-M4	263	0.535	2.01	4.45	0.017	321	65.0	445	1599	124	263	94.5	57.5	152	6759	9728	37.0
AHE32-M5	88.1	0.589	2.00	4.92	0.056	354	21.5	71.3	77.0	39.0	75.4	54.1	32.9	87.0	1101	1826	20.7
AHE32-M6	132	1.04	1.96	8.86	0.067	68.7	18.6	24.7	12.3	188	152	101	61.4	162	1210	1836	13.9
AHE40-M1	10.2	0.193	1.95	1.65	0.163	0.2	0.5	0.2	5.9	0.5	11.7	0.55	0.3	0.88	98.0	118	11.6
AHE40-M2	501	8.28	1.95	70.9	0.141	769	233	372	445	89.6	139	49.5	30.1	79.6	719	2847	5.7
AHE40-M3	661	4.90	1.95	42.0	0.069	336	314	431	122	76.3	455	5.8	3.5	9.3	1412	3155	5.2
AHE40-M4	19.0	1.21	2.00	10.1	0.531	194	14.4	219	52.0	14.4	59.2	12.2	7.4	19.6	577	1150	60.5
AHE40-M5	40.1	2.31	1.95	19.8	0.493	61.3	21.6	105	32.5	205	90.7	4.2	2.6	6.8	189	712	17.8
AHE40-M6	30.6	1.52	2.00	12.7	0.415	280	70.9	284	80.0	98.7	184	6.6	4.0	10.6	473	1482	48.4

[a] Dermal exposure values do not reflect default 50% adjustment to hands and face/neck measurements.
[b] Average flow rate (Start flow rate + End flow rate / 2).
[c] Inhalation Exposure (ug) = Adjusted OVS Tube Residue (ug) * [Breathing Rate (16.7 L/min) ÷ Avg. Pump Flow Rate (L/min)]
[d] Inhalation Unit Exposure = Inhalation Exposure (ug) ÷ AaiH (lbs)
[e] LA = lower arm; UA = upper arm; FT = front torso; RT = rear torso; LL = lower leg; UL = upper leg
[f] Face/neck residues are adjusted (extrapolated) to account for portions of face and neck not wiped due to PPE worn.
[g] Portion of head not measured (wiped) = PPE-adjusted face/neck residue X extrapolation ration (0.610). Based on AHETF SOP 9.K.
[h] Whole Head/Neck Residue = PPE-adjusted face/neck residue + non-wiped head residue.
[i] Total Dermal Exposure (ug) = LA + UA + FT + RT + LL + UL + Whole Head + Hands
[j] Dermal Unit Exposure (ug/lb ai) = Total Dermal Exposure (ug) ÷ AaiH (lbs)

13544

R190683

Chemical Name:

PC Code:	
HED File Code:	**12000 Exposure Reviews**
Memo Date:	**3/11/2011**
File ID:	**00000000**
Accession #:	**000-00-0137**

HED Records Reference Center
3/15/2011